UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

REYDON RECKER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. CIV-19-950-G**
	)	
C.R. BARD, INC. et al.,	)	
	)	
Defendants.	)	

ORDER

Now before the Court are the Motions to Dismiss Plaintiff's First Amended Complaint (Doc. Nos. 13, 29) filed by Defendants Bard Access Systems, Inc. and C.R. Bard, Inc. Plaintiff has responded in opposition (Doc. No. 14, 37), and Defendant Bard Access Systems, Inc. has replied (Doc. No. 17). Having reviewed the parties' submissions, the Court makes its determination.

BACKGROUND

This products-liability matter involves the Bard PowerPort M.R.I. Implantable Port ("PowerPort"), a device designed to facilitate the repeated delivery of medication into the vascular system. *See* Am. Compl. (Doc. No. 11) ¶¶ 11-12. The device, which is commonly used for the administration of chemotherapy, is surgically implanted under a patient's skin. *See id.* ¶¶ 12, 17. In October 2017, Plaintiff had a PowerPort implanted to receive chemotherapy. Plaintiff alleges that within three months, the device malfunctioned by detaching and migrating into his right internal jugular vein. As a result, Plaintiff underwent surgery to remove the device and to correct complications allegedly caused by the

malfunction. *See id.* ¶¶ 33, 36. Plaintiff now seeks redress for "an unnecessary major surgery, increased risk of future severe and permanent injuries, severe emotional distress, [and] ongoing fear and anxiety from future injuries." *Id.* ¶ 37. He brings claims of negligence, breach of implied warranty, breach of express warranty, and fraudulent concealment, as well as claims of strict products liability for failure to warn, manufacturing defect, and design defect.

STANDARD OF DECISION

In analyzing a motion to dismiss under Rule 12(b)(6), the court "accept[s] as true all well-pleaded factual allegations in the complaint and view[s] them in the light most favorable to the plaintiff." *Burnett v. Mortg. Elec. Registration Sys., Inc.*, 706 F.3d 1231, 1235 (10th Cir. 2013). A complaint fails to state a claim on which relief may be granted when it lacks factual allegations sufficient "to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (footnote and citation omitted); *see also Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008) ("[T]o withstand a motion to dismiss, a complaint must contain enough allegations of fact to state a claim to relief that is plausible on its face." (internal quotation marks omitted)). Bare legal conclusions in a complaint are not entitled to the assumption of truth; "they must be supported by factual allegations" to state a claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

DISCUSSION

In his Response to Defendants' Motions, Plaintiff expressly conceded that dismissal is appropriate as to his claims of breach of implied warranty and fraudulent concealment. *See* Pl.'s Resp. at 2. Accordingly, the Court considers only Defendants' arguments regarding the remaining claims.

I. Negligence

"Under Oklahoma law, all negligence claims require proof of a duty, a breach of that duty, and causation." *Martinez v. Angel Expl., LLC*, 798 F.3d 968, 974 (10th Cir. 2015) (citing *Scott v. Archon Grp., L.P.*, 191 P.3d 1207 (Okla. 2008)).[1] Defendants assert that the Amended Complaint contains only a formulaic recitation of the elements of negligence, rather than facts sufficient to support a plausible claim. Defendants broadly object that the pleading does not specify the applicable standard or care, any acts or omissions constituting a breach of care, or how the breach of care proximately caused Plaintiff's injuries. *See* Def.'s Mot. (Doc. No. 13) at 11. This nominal challenge fails to demonstrate any pleading deficiencies.

In his pleading, Plaintiff alleges that Defendants owed him "a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the PowerPort." Am. Compl. ¶ 49. Plaintiff then delineates multiple alleged breaches of that duty, including that Defendants

[1] In Oklahoma, a plaintiff injured by a defective product is not foreclosed from asserting a freestanding negligence claim in addition to claims of strict products liability. *See Braswell v. Cincinnati Inc.*, 731 F.3d 1081, 1093 n.4 (10th Cir. 2013).

failed to properly test the device or provide adequate warning of its "dangerous propensity . . . to migrate and/or dislodge" and that Defendants "continu[ed] to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or should have known of its adverse effects." *Id.* ¶¶ 44, 50. As for causation, Plaintiff attests that the device was appropriately placed according to its instructions for use but that defects in the device caused it to detach and migrate within his body, requiring major surgery. *Id.* ¶¶ 34, 36. Plaintiff states that his physician relied upon Defendants' representations in their instructions and advertisements to Plaintiff's detriment. *Id.* ¶ 43.

Viewed in Plaintiff's favor, the factual allegations of the Amended Complaint plausibly show that Defendants acted negligently. Plaintiff's negligence claim therefore survives Defendants' Rule 12(b)(6) challenge.

II. Strict Products Liability Claims

When a plaintiff sues a supplier or retailer under a strict products liability theory, the plaintiff must establish "(1) that the product caused plaintiff's injury; (2) that the defect existed in the product at the time of sale or at the time it left the retailer's possession and control; and (3) that the defect made the product unreasonably dangerous." *Wheeler v. HO Sports Inc.*, 232 F.3d 754, 756 (10th Cir. 2000) (citing *Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353 (Okla. 1974)); *see Holt v. Deere & Co.*, 24 F.3d 1289, 1292 (10th Cir. 1994). The defect alleged "may be the result of a problem in the product's design or manufacture, or it may be the result of inadequate warnings regarding use of the product." *Wheeler*, 232 F.3d at 757 (internal quotation marks omitted). Here, Plaintiff has alleged that the PowerPort was defective in all three respects.

a. Failure to Warn

"The manufacturer of a product has a duty to warn the consumer of potential dangers which may occur from the use of the product when it is known or should be known that hazards exist." *McKee v. Moore*, 648 P.2d 21, 23 (1982). Even if a product is designed and manufactured faultlessly, inadequate warnings can still expose the manufacturer to liability. *See id.* The duty to warn is a continuing duty that "requires the manufacturer to maintain current information gleaned from research, adverse reaction reports, scientific literature and other available methods." *Id.* at 24. To establish a failure-to-warn claim, a plaintiff must show both that the product caused the injury and that the manufacturer breached a duty to warn of potential dangers. *See Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1017 (10th Cir. 2001). In showing causation, a plaintiff must demonstrate that the failure to warn was "a substantial contributing factor in bringing about the harm in question." *Id.*

When a plaintiff raises a failure-to-warn claim where a medical device was supplied to a doctor or surgeon rather than to the patient directly, Oklahoma's learned intermediary doctrine applies. *See Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla. 1997). Under the learned intermediary doctrine, manufacturers are shielded from liability "if the manufacturer adequately warns" the medical professional that prescribes the drug or implants the medical device. *Id.*; *see McKee*, 648 P.2d at 25. To establish causation in the learned intermediary context, a plaintiff must show that, "had defendant issued a proper

warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Eck*, 256 F.3d at 1018.

Here again, Defendants submit that Plaintiff's allegations are merely conclusory. The Court disagrees. Plaintiff specifically alleges that the PowerPort detached and migrated, that Defendants had knowledge of numerous reports of such migration and associated injuries, and that Defendants failed to warn physicians of these dangers. *See* Am. Compl. ¶¶ 28, 38, 50-64. Plaintiff further alleges that, "had Defendants provided adequate warnings, Plaintiff and his physicians would not have used the device." *Id.* ¶ 67. Plaintiff's well-pleaded allegations, viewed in his favor, are sufficient to meet the plausibility threshold.

Defendants also point to the PowerPort's Instructions for Use, which Defendants attached to their Motion. *See* Def.'s Mot. at 17 n.2. According to Defendants, the document "includes many of the same risks alleged" in the Amended Complaint. *Id.* at 17. Defendants do not argue, however, that the document warns of all the risks alleged in Plaintiff's pleading, including detachment and migration. Nor do Defendants elaborate on their contention by discussing the specific warnings contained in the Instructions for Use. Without more, the Court cannot at this stage determine if the warnings contained in the Instructions for Use sufficiently encompass the risks alleged. Accordingly, Plaintiff's failure-to-warn claim may proceed.

b. Manufacturing Defect

When the defect is alleged to stem from the manufacture of the product, the plaintiff must ultimately show that the product "deviates in some material way from its design or

performance standards." *Wheeler*, 232 F.3d at 757 (internal quotation mark omitted). In his pleading, Plaintiff alleges that the PowerPort implanted in him "differed from [the] Defendants' intended result and/or from other ostensibly identical unit[s] of the same product line," and "varied from its intended specifications." Am. Compl. ¶¶ 70-71. Defendants argue that these allegations are merely conclusory and that the claim fails because Plaintiff did not identify the PowerPort's design specifications or explain how the implanted device deviated therefrom. *See* Def.'s Mot. at 19.

While errors in the manufacturing process "are often established by showing that a product, as produced, failed to conform with the manufacturer's specifications," Defendants have not shown that a plaintiff's failure to describe those specifications in detail, or to describe the defective product's deviation from those specifications, is fatal at the pleading stage. *Wheeler*, 232 F.3d at 757. In many cases, a product's design specifications will be complex and knowable to the plaintiff only through the course of discovery. Here, Plaintiff notes that the PowerPort consists of "two primary components: an injection port and a polyurethane catheter." Am. Compl. ¶ 13. Plaintiff then identifies the catheter as the component that malfunctioned. *See id.* ¶ 36. Plaintiff additionally alleges that the manufacturing defect caused his injuries, and that the PowerPort contained the manufacturing defect at the time it left Defendants' possession and control. *Id.* ¶¶ 36, 70, 73. Viewed in Plaintiff's favor, Plaintiff's allegations of a manufacturing defect plausibly give rise to an entitlement to relief.

c. Design Defect

"A product is defective in design if something about that design 'renders it less safe than expected by the ordinary consumer.'" *Wheeler*, 232 F.3d at 758 (quoting *Lamke v. Futorian Corp.*, 709 P.2d 684 (Okla. 1985)). In his pleading, Plaintiff asserts that a design defect caused the PowerPort's catheter to detach and migrate and that the defect was present at the time the product left Defendants' possession and control. *See* Am. Compl. ¶¶ 74-80.

Defendants primarily complain that Plaintiff failed to "identify any particular problem in the design." Def.'s Mot. at 20. But, as noted, Plaintiff discusses the two components of the PowerPort and expressly states that the catheter component malfunctioned by detaching from the injection port. *See* Am. Compl. ¶¶ 13, 36. Plaintiff further contends that the PowerPort caused similar adverse events in many others. *See id.* ¶ 27. Because it is evident that the alleged defect involves the catheter and the connection point between the catheter and injection port, greater detail as to the PowerPort's design is not required to provide Defendants fair notice of this claim.

III. Breach of Express Warranty

Unlike Plaintiff's negligence and product-liability causes of action, Plaintiff's breach-of-express-warranty claim sounds in contract and is governed by Oklahoma's Uniform Commercial Code. *See Kirkland*, 521 P.2d at 1357. As relevant here, express warranties include "(a) [a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain" and "(b) [a]ny

description of the goods which is made part of the basis of the bargain." Okla. Stat. tit. 12A, § 2-313(1)(a)-(b).

In his pleading, Plaintiff broadly asserts that Defendants, "through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the PowerPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use." Am. Compl. ¶ 90. In his Response to Defendants' Rule 12(b)(6) challenge, Plaintiff points solely to the Instructions for Use as the mechanism by which the express warranties were made. *See* Pl.'s Resp. at 10. Nowhere, however, does Plaintiff identify the specific statements on which he bases this claim.

While the complexity of certain facts may merit broad descriptions under *Twombly/Iqbal*, there is no great complexity to identifying affirmative statements. *See Khalik v. United Air Lines*, 671 F.3d 1188, 1191 (10th Cir. 2012) ("[T]he nature and specificity of the allegations required to state a plausible claim will vary based on context." (internal quotation marks omitted)). Plaintiff's failure to do so renders his allegations conclusory. Thus, he fails to state a plausible claim for breach of express warranty. *See Robbins*, 519 F.3d at 1247 (explaining that if allegations in a complaint "are so general that they encompass a wide swath of conduct, much of it innocent, then the plaintiffs have not nudged their claims across the line from conceivable to plausible" (internal quotation marks omitted)).

IV. Request to Amend

In his Response, Plaintiff requests that should the Court determine that any of his claims fail to satisfy the federal pleading standard, Plaintiff be granted leave to file a Second Amended Complaint. Plaintiff may file a motion to amend his pleading that complies with Local Civil Rules 7.1 and 15.1 within fourteen days of this Order.

CONCLUSION

For the reasons stated herein, Defendants' Motions to Dismiss (Doc. Nos. 13, 29) are GRANTED IN PART and DENIED IN PART. Plaintiff's claims of breach of implied warranty and fraudulent concealment are dismissed with prejudice. Plaintiff's claim of breach of express warranty is dismissed without prejudice. Defendants' motions are denied in all other respects.

IT IS SO ORDERED this 30th day of September, 2020.

Charles B. Goodwin

CHARLES B. GOODWIN
United States District Judge